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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,114	07/25/2003	Peter Paul Zilla	P-8794.05 Continutation 2	3869
Kenneth J. Coll	7590 05/18/200 ier	EXAMINER		
Medtronic, Inc.		WILLSE, DAVID H		
710 Medtronic Parkway N.E. Minneapolis, MN 55432			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) Integr. 114 Integr. 114							
Examiner Dave Willies 3738 37			Application No.	Applicant(s)			
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE of THIS COMMUNICATION). Estandation of them may be available under the provisions of 37 CPR 1.738(b). In so event, however, may a reply be limity filled and 52 No. (MONTHS) from the mailing date of the communication. False to reply within the provision of 37 CPR 1.738(b). In so event, however, may a reply be limity filled and 52 No. (MONTHS) from the mailing date of this communication. False to reply within the trade than the months after the mailing date of this communication, even if limity filled, may reduce any control present term adjustment. See 37 CPR 1.738(b). Status 1) Responsive to communication(s) filled on OT November 2005 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Exparte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) is/are allowed. 4) Claim(s) is/are allowed. 6) Claim(s) is/are allowed. 6) Claim(s) is/are allowed. 6) Claim(s) is/are allowed. 7) Claim(s) is/are allowed. 9) The specification is objected to by the Examiner. 10) The drawing(s) filled on is/are: a) sceepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. Sea 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is ma	Office Action Summary		10/627,114	ZILLA ET AL.			
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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 71, 72, 74, 76, 78, 79, and 82-84 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Alt, US 2004/0039438 A1. The scaffold 32 includes interconnected pores bordered by microspheres bonded to one another; said pores are defined by surfaces that are spherically concave (Figure 2; paragraph 0033; etc.) and thus uniformly shaped. The ingrowth matrix generally involves drugs incorporated in a biodegradable carrier (e.g., paragraph 0041) and comprises a concentration gradient by virtue of the larger reservoir or repository toward the base layer 30 (paragraphs 0011, 0034, and 0040). Regarding claims 74, 76, 78, and 79, viruses and genes (abstract, last sentence; paragraphs 0042 and 0044) inherently possess proteins and peptides. Regarding claim 82, the stent may take on a helical form (paragraphs 0021 and 0030), wherein the interconnecting channels would collectively be helically oriented. Regarding claim 83: paragraph 0031. Regarding claim 84, the term "spherical" means "[o]f or pertaining to a

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sphere" (Webster's II New Riverside University Dictionary, 1984); the pore shapes pertain to a sphere in that they are defined by adjacent microspheres.

Claims 73, 75, 77, 80, 81, and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt, US 2004/0039438 A1. Regarding claim 73, hydrogels were well known in the art at the time of the present invention and would have been obvious in order to contain medicaments in solution. Regarding claims 75, 77, and 80, materials such as collagen and growth factor would have been obvious in order to facilitate endothelial cell growth and/or gene transfer. Regarding claim 81, polyethylene glycol was well known as a base for pharmaceuticals and would thus have been obvious to the ordinary practitioner for carrying certain types of drugs. Regarding claims 85-87, stents are commonly used for affixing vascular grafts and heart valves (including sewing rings) within the circulatory system; to incorporate the Alt coating system into such stents would have been obvious in order to provide drug delivery when indicated.

The Applicant's remarks have been considered. The Applicant argues that "it would be clear to one of skill in the art that merely changing the *size* of a reservoir or repository, and correspondingly changing the *volume of material* with which it is filled, does not change the *concentration* of the material within the reservoir or repository" (Applicant's reply of February 27, 2007: page 4, lines 15-18; emphasis in original). The word "concentration" is defined as "the amount of a component in a given area or volume" (*Merriam Webster's Collegiate Dictionary*, 10th ed.: 1996). In present claim 71, line 4, the "material" as claimed may be interpreted as the material of the matrix itself or as a second material in the form of a drug or the like. Because of the larger reservoir or repository toward the base layer 30 in the Alt device, there exists a greater amount of matrix material (or biodegradable carrier) and a greater amount of drug in overall unit

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volumes (including volume occupied by microspheres) nearer to the base layer. The term "concentration gradient" is not defined in a manner prescribed by MPEP § 2111.01; the examiner must give the present claims their broadest reasonable interpretation (MPEP § 2111). Moreover, once implanted, continuing *diffusion* of the carrier from inner portions of the scaffold 32 to outer portions (paragraph 0041, last sentence) necessitates concentration gradients of the carrier and hence the drug. Regarding claim 84, the shapes of the spaces between the spherical particles in the Alt implant are primarily defined by portions of spherical surfaces; said shapes thus "pertain" to a sphere.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse Primary Examiner Art Unit 3738